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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/085,820 05/28/98 WANG H CIT98-01PA

HM12/1024

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EXAMINER

ANDRES, J

ART UNIT

PAPER NUMBER

1646

14

DATE MAILED:

10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/085,820

Applicant(s)

WANG ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-66 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 11, 13, 15-40, 44-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7-10, 41 and 42 is/are rejected.
- 7) ☒ Claim(s) 12, 43 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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Response to Arguments

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Objections/Claim Rejections Withdrawn

2. The objection to claim 14 is withdrawn in response to applicant's amendment canceling claim 14. The rejection of claims 1-3, 5, and 7 on the basis that the identification of factors enhancing interaction between ephrin B2 and ephB4 was not enabled by the specification is withdrawn in response to applicant's arguments. The rejection of claims 8-10, 12, and 14 on the basis that methods targeting drugs using agents directed against ephrin-B2 were not enabled by the specification is withdrawn in response to applicant's arguments. The rejection of claim 43 as lacking enablement for polypeptides comprising the extracellular domain of ephB4 is similarly withdrawn in response to applicant's arguments.

Claim Rejections Maintained

3. The rejection of claims 41 and 42 as not enabled by the specification is maintained. Applicant suggests on p. 4 of the amendment filed on August 4, 2000 that the examiner has misinterpreted claims 41-43. The examiner understands that the claims are drawn to the use of

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soluble extracellular domains; the species election was to angiogenic factors affecting artery-specific molecules. Thus presumably an extracellular domain of a vein-specific protein, ephB4 in claim 43, would be administered with the intent of promoting angiogenesis. The rejection of this claim was based on the lack of predictability of what sequences comprising this domain would function as claimed. This rejection of claim 43 has been withdrawn, as stated above, in response to applicant's arguments on p.2. The examiner agrees that the specification is enabling for methods based on the binding of ephrinB2 to ephB4. However, the examiner reiterates that, while the use of polypeptides consisting of the extracellular domain of a known protein is in fact art standard, the use of polypeptides comprising any extracellular domain of any vein-specific cell surface protein, including those not yet described, is not and the rejection of claims 41 and 42 is maintained for the reason set forth below.

4. The rejection of claims 1-3, 5, 8-10, 41, and 42 on the basis that the specification is not enabling for any molecules other than ephrinB2 and ephB4 is maintained. The identification of one artery-specific molecule by another (Shutter et al., Genes and Dev., Vol.14, pp. 1313-1318, 2000) does not indicate that the specification enabled the claimed invention at the time of filing. Although applicant can present information regarding the enablement of a claimed invention after filing, the methods must have been taught at the time of filing. The instant application does not provide sufficient guidance to enable one of skill to predictably identify and thus to use other artery- or vein- specific molecules. No specific characteristics or structures of artery- or vein-specific proteins are set forth; since ephrins and their receptors are widely distributed, the prior art encompassing their structural and functional requirements provides no guidance for identifying any other species of artery- or vein- specific molecule. It is this lack of predictability

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of a successful outcome, combined with the amount of experimentation required, that renders the necessary experimentation undue. See MPEP 2164.03.

5. Claim 1-3, 5, 8-10, 41, and 42 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a genus of interacting artery- and vein- specific molecules. Applicant has described one species, the EphB4/ephrin b2 system. However, applicant has not described the structural or functional characteristics sufficient to identify other members of this genus, including other members of the ephrin/Eph family. No features of these molecules responsible for their claimed function are described, nor or any other members of the genus described. Applicant has therefore described neither a representative number of members of the genus nor the relevant structural features of the genus, and one of skill in the art would not be able to identify other members of the genus based on the instant disclosure. One of skill would not therefore recognize that applicant had possession of the invention as broadly claimed at the time the application was filed.

6. The rejection of claims 1-3, 5, and 7 under 35 U.S.C. 112, second paragraph, is maintained. Pages 21-23 detail methods of evaluating molecules that affect interactions between artery- and vein-specific molecules but at no point define the limitations of such an interaction, particularly as distinct from "binding", as instantly claimed. This rejection can be overcome by limitation of the claims to read "specific binding".

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7. Claims 12 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 12 AND 43 ARE OBJECTED TO. CLAIMS 1-3, 5, 7-10, 41, AND 42 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

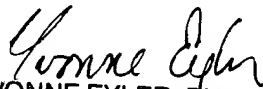
All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

October 20, 2000


YVONNE EYLER, PH.D
PRIMARY EXAMINER